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| APPLICATION NO.                                  | FILING DATE                | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|----------------------------|----------------------|---------------------|------------------|
| 10/616,125                                       | 07/08/2003                 | Axel Grandt          | JM-040              | 2218             |
| 57360<br>WORKMAN N                               | 7590 10/30/200<br>IYDEGGER | 8                    | EXAMINER            |                  |
| 1000 EAGLE C                                     | GATE TOWER,                |                      | PELLEGRINO, BRIAN E |                  |
| 60 EAST SOUTH TEMPLE<br>SALT LAKE CITY, UT 84111 |                            |                      | ART UNIT            | PAPER NUMBER     |
|  |                            |                      | 3738                |                  |
|  |                            |                      |                     |                  |
|  |                            |                      | MAIL DATE           | DELIVERY MODE    |
|  |                            |                      | 10/30/2008          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.   | Applicant(s)   |  |  |  |  |
|--|---|--|--|--|--|--|
|  | 10/616,125  | GRANDT, AXEL   |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit   |  |  |  |  |
|  | Brian E. Pellegrino   | 3738   |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | ears on the cover sheet with the c  | orrespondence address  |  |  |  |  |
|  | / IO OFT TO EVEIDE A MONTH!   | 0) OD THIDTY (00) DAYO   |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |  |
| Status   |   |  |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on <u>15 Au</u>   | ugust 2008.   |  |  |  |  |  |
|  | action is non-final.  |  |  |  |  |  |
| 3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |   |  |  |  |  |  |
| closed in accordance with the practice under E   | x parte Quayle, 1935 C.D. 11, 45  | 53 O.G. 213.   |  |  |  |  |
| Disposition of Claims  |   |  |  |  |  |  |
| 4)⊠ Claim(s) <u>1-10,13-17,19,21-23,26 and 27</u> is/are   | pending in the application.   |  |  |  |  |  |
| 4a) Of the above claim(s) <u>3,4,9,10,13,14 and 19</u> is/are withdrawn from consideration.  |   |  |  |  |  |  |
| 5) Claim(s) is/are allowed.  |   |  |  |  |  |  |
| 6)⊠ Claim(s) <u>1,2,5-8,15-17,21-23,26 and 27</u> is/are rejected.   |   |  |  |  |  |  |
| 7) Claim(s) is/are objected to.  |   |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or  | r election requirement.   |  |  |  |  |  |
| Application Papers   |   |  |  |  |  |  |
| 9) The specification is objected to by the Examine   | r.  |  |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.   |   |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |  |  |  |  |  |
| Replacement drawing sheet(s) including the correct   | ion is required if the drawing(s) is obj  | ected to. See 37 CFR 1.121(d).   |  |  |  |  |
| 11)☐ The oath or declaration is objected to by the Ex  | aminer. Note the attached Office  | Action or form PTO-152.  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  |   |  |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:   |   |  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |   |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |   |  |  |  |  |  |
| 3. Copies of the certified copies of the prior   | •   | ed in this National Stage  |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |   |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |  |  |  |  |  |
|  |   |  |  |  |  |  |
| Au . I   |   |  |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)   | A) Interview Summers  | (PTO-413)  |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date  |   |  |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08)  5) Notice of Informal Patent Application   |   |  |  |  |  |  |
| Paper No(s)/Mail Date 6) U Other:  |   |  |  |  |  |  |

## **DETAILED ACTION**

## Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/15/08 has been entered.

## Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,2,5,6,15-17,21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leone et al. (5882335) in view of Fontaine (5443498) and Brown et al. (6071305). Leone et al. illustrate (Figs. 1,2) a stent 12 formed of a tubular member 28 with a lumen therein and a multiplicity of pores 29 in fluid communication with the lumen. Leone also discloses a therapeutic agent is delivered into the lumen via the proximal end (col. 3, lines 47-49) and is eluted from the stent into the vessel it is implanted in, col. 3, lines 61-65. Leone does disclose other stent designs can be used, col. 4, lines 38-40. However, Leone et al. fail to explicitly disclose the stent is a plurality of tubular members with circumferential rings having upper peaks connected to lower

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peaks of adjacent tubular members or the material containing the drug is a bioabsorbable polymer. Fontaine teaches (Figs. 5,12) a stent with a plurality of tubular members having circumferential rings with the peaks and valleys of adjacent rings coupled together. Fontaine also teaches that the ring structures provide more rigidity and less likely to pulsate or rub in the vessel, col. 2, lines 36-42, col. 3, lines 63-66. Brown et al. teach (Fig. 2) a stent with circumferential sections including a channel 20 for therapeutic material. Brown discloses that bioabsorbable polymers (col. 8, lines 62-65, col. 9, line 1, col. 10, lines 19-21) are used as means for controlling release from the channel into the lumen of the patient. It would have been obvious to one of ordinary skill in the art to use a absorbable polymer to hold the drug as taught by Brown et al. disposed in the tubular members of the stent of Leone et al. as modified by Fontaine to have a plurality of circumferential rings to increase the strength of the stent to maintain lumen patency. Regarding claims 5,22 the distance between the first pore and second pore would be spaced apart at a distance different than the first pore to the third pore. With respect to claim 17, Leone discloses the tubular member of the stent can be made of shape memory, col. 4, lines 6-9.

Claims 7,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leone et al. '335 in view of Fontaine '498 and Brown et al. '305 as applied to claim 1 above, and further in view of Harry (2002/0038146). Leone et al. as modified by Fontaine and Brown is explained supra. Brown does disclose the pores can be any type of opening or shape, col. 6, lines 15-18. However, Leone et al. in view of Fontaine and Brown fail to disclose the pores vary in size or shape with respect to one another.

Harry teaches (Figs. 2,3) pores varying in size on the stent. Harry also teaches (Fig. 8) pores that vary in shape on the stent. It would have been obvious to one of ordinary skill in the art to vary the size or shape of the pores as taught by Harry with the stent of Leone as modified by Fontaine and Brown to provide different amounts of therapeutic material released from the stent.

Claims 26,27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leone et al. '335 in view of Fontaine '498 and Brown et al. '305 as applied to claim 1 above, and further in view of Sirhan et al. (2003/0083646). Leone et al. as modified by Fontaine and Brown is explained supra. Brown does teach various agents can be used with the stent, col. 5, lines 1-3. However, Leone et al. in view of Fontaine and Brown fail to disclose the circumferential rings contain different therapeutic agents. Sirhan et al. teach that different locations can contain different therapeutic drugs, paragraph 34. It would have been obvious to one of ordinary skill in the art to place different therapeutic agents in different locations as taught by Sirhan et al. with the stent of Leone as modified by Fontaine and Brown to provide different therapeutic material to different areas of a vessel and to limit any adverse reaction between varying drugs.

## Response to Arguments

Applicant's arguments with respect to claims 1,15,23 have been considered but are most in view of the new ground(s) of rejection.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700 /Brian E Pellegrino/ Primary Examiner, Art Unit 3738